IN THE UNITED STATES COURT OF FEDERAL CLAIMS

ALEX and TESS BECHEL, *Parents of* G.J.B., *a minor*,	)	
Petitioners,	)	No. 16-887
v.	)	Filed: November 20, 2023
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	Re-issued: December 15, 2023[*]
Respondent.	)	

OPINION AND ORDER

Petitioners Alex and Tess Bechel ("Petitioners") seek review of a decision denying compensation under the National Vaccine Injury Compensation Program ("Vaccine Act"). Petitioners filed a petition for compensation alleging that their son, G.J.B., suffered from encephalopathy, epilepsy, seizures, delirium, confusion, altered mental state, and other injuries caused by several vaccines he received on July 29, 2013. On May 22, 2023, the Chief Special Master denied Petitioners' claim, finding that Petitioners had not shown by a preponderance of evidence that they were entitled to compensation. Before the Court is Petitioners' Motion for Review of the Chief Special Master's entitlement decision pursuant to Rules 23 and 24 of the Vaccine Rules of the United States Court of Federal Claims ("Vaccine Rules"). For the reasons discussed below, the Court **DENIES** Petitioners' Motion.

[*] The Court issued this opinion under seal on November 20, 2023, and directed the parties to file any proposed redactions by December 5, 2023. As the parties do not propose any redactions, the Court reissues the opinion publicly in full.

I. BACKGROUND

A. G.J.B.'s Medical History Prior to Vaccination and Onset of Symptoms

G.J.B. was born a healthy, full-term infant on May 13, 2009, without significant neonatal problems. Pet'rs' Ex. 2 at 7–8, ECF No. 3-2. Though G.J.B. experienced largely normal development through toddlerhood, medical records contain a few notable issues. First, at his 18-month checkup, Ms. Bechel reported that G.J.B. complained of "light hurting [his] eyes" and displayed "some odd tendencies" such as "hat[ing] having things on his hands[.]" Pet'rs' Ex. 3 at 16, ECF No. 3-4. Second, medical records from his three- and four-year visits reflect that G.J.B. experienced issues with speech development. *Id.* at 34–36, 43–47; ECF No. 3-2 at 1–8. On October 16, 2012, G.J.B. underwent a speech/language evaluation, and it was determined that he had a delay in articulation; speech therapy was recommended. *See* Pet'rs' Ex. 16 at 2–3, ECF No. 12-2.

At his four-year-old check up on July 29, 2013, G.J.B. was given the Kinrix (DTaP and IPV);[1] measles, mumps, rubella ("MMR"); and varicella ("VAR") vaccines. ECF No. 3-2 at 5; ECF No. 3-4 at 47. Ms. Bechel stated that the day following his vaccinations she "noticed his legs were a little red and swollen around the site of injection" and "G.J.B. started complaining of a headache that evening and continued to complain over the next few days off and on." Pet'rs' Ex. 8 ¶ 2, ECF No. 5-2. G.J.B.'s grandmother averred that on July 31, 2013, G.J.B. developed "severe swelling in both of his thighs and a headache." Pet'rs' Ex. 10 ¶ 2, ECF No. 5-4. On August 3, 2013, five days following the administration of the vaccines, Ms. Bechel contacted Central Baptist Hospital for an assessment of G.J.B.'s condition. Pet'rs' Ex. 5 at 1, ECF No. 3-6. She reported

[1] "DTaP" is the acronym for diphtheria-tetanus-acellular pertussis vaccine, and "IPV" is the acronym for polio vaccine.

that G.J.B. could not remember some words and did not know his name when asked. *Id*. The "onset/duration" was noted as "today." *Id*. The record of this communication also indicates that G.J.B. received his four-year vaccinations on the previous Monday, and that he "had speech problems in the past with stuttering." *Id*. No other physical issues or newly observed symptoms were recorded at the time, and Ms. Bechel reported G.J.B. to have been afebrile. *Id*. The nurse advised Ms. Bechel to seek emergency treatment "immediately," although Petitioners did not do so. *Id*.

The following day, August 4, 2013, a nurse with Pediatric and Adolescent Associates followed up with Ms. Bechel. ECF No. 3-4 at 48. Ms. Bechel stated that she had not taken G.J.B. to the emergency room and that he was still stuttering and becoming frustrated. *Id.* Medical records note that "mom thinks this is all related to the 4 yr vaccines he got a few days ago." *Id.* The same note memorialized Ms. Bechel's reporting that G.J.B. did not have a history of these behaviors in the past and did not have any other injury or illness. *Id*. Ms. Bechel was advised to monitor G.J.B.'s condition and bring him in the next day if concerns continued. *Id.*

On August 5, 2013, G.J.B.'s grandmother performed an at-home electroencephalogram ("EEG") test on G.J.B.[2] Pet'rs' Ex. 20 at 1–23, ECF No. 15-1; ECF No. 5-4 ¶ 4. She averred in an affidavit that the study results appeared "abnormal" to her, and she recommended that G.J.B. be taken to a physician and pediatric neurologist for a full work up. ECF No. 5-4 ¶ 5. Ms. Bechel took G.J.B. to a pediatrician on August 6, 2013, where she reported that G.J.B. complained of a headache after receiving his vaccinations and had woken up the morning of August 3, 2013 "stuttering really bad" with a "blank look on his face"—a novel behavior—followed by off-and-

[2] Medical records indicate that G.J.B.'s grandmother is an experienced EEG technologist with experience in neurological testing.

on stuttering and an instance where he forgot his name. ECF No. 3-4 at 50–52. Ms. Bechel shared that G.J.B. had manifested some issues with speech before vaccination and was enrolled in a Head Start program but did not previously stutter. *Id.* The pediatrician observed G.J.B. stutter several times during the visit, although during examination G.J.B. was alert and oriented with no focal deficits. *Id.* The pediatrician diagnosed G.J.B. with "stuttering" and referred him to Cincinnati Children's Hospital for a neurology consultation. *Id.*

B. Diagnostic Testing, Initial Treatment, and Follow-up Treatment

On August 7, 2013, G.J.B. was seen by a neurologist at St. Joseph's Hospital and admitted for a 24-hour video EEG study. *See* Pet'rs' Ex. 12, ECF No. 10-1. The study yielded abnormal results and displayed 16 events, consisting of stuttering of speech or repeating words, with no other clinical change noted. *Id.* at 34–35. The study specifically revealed epileptiform discharges and suggested the possibility of multifocal/generalized epileptogenicity. *Id.* G.J.B. was subsequently seen by Dr. Marissa Vawter at Cincinnati Children's Hospital, where Ms. Bechel provided a detailed history of G.J.B.'s health since his July vaccinations. Pet'rs' Ex. 6 at 1–35, ECF No. 4-1. During this visit, Ms. Bechel also informed Dr. Vawter that G.J.B. had a personal and family history of headaches and difficulties with enunciation. *Id.* at 3. On physical examination, G.J.B. was alert and his detailed neurological exam was normal. *Id.* at 4–5. Dr. Vawter opined that G.J.B. had experienced at least two clinical seizures in the past ten days, singling out "the episodes where he had abnormal verbal speech patterns and/or repetitions." *Id.* at 5. Dr. Vawter also documented that G.J.B. met the criteria for epilepsy with "unknown etiology" and started him on Keppra, an anti-seizure medication, to help stabilize and control his seizure activity. *Id.*

On November 12, 2013, Dr. Vawter examined G.J.B. again. *See id.* at 74–111. Ms. Bechel reported that G.J.B. had experienced no seizures or episodes of stuttering since the initial visit in

August, but the Keppra caused significant irritability and so alternative medications were discussed. *Id.* at 76, 79–80. G.J.B. saw Dr. Vawter again in February 2014, at which time Ms. Bechel reported that G.J.B. had experienced only one seizure since changing anti-seizure medications. *Id.* at 124. Ms. Bechel also expressed concerns about the possibility of "developmental regression." *Id.*

In March 2014, G.J.B. was evaluated at Cincinnati Children's Rheumatology service for an initial evaluation of joint pain. ECF No. 3-4 at 135–38. On physical examination, G.J.B. displayed increased flexibility, particularly in the ankles and knees, and laboratory testing was recommended to evaluate G.J.B. for a possible underlying autoimmune or thyroid condition. *Id.* Around this time, G.J.B. also underwent an ophthalmological evaluation, which revealed hyperopia.[3] Pet'rs' Ex. 13 at 2–3, ECF No. 11-1. In May 2014, treaters noted that testing for autoimmune/rheumatologic conditions had produced normal results, and physical therapy ("PT") was recommended for G.J.B.'s joint pain. ECF No. 3-4 at 139–40. Subsequent PT evaluations revealed both functional weakness and gross motor delays. Pet'rs' Ex. 7 at 4–7, ECF No. 5-1. G.J.B. continued to experience headaches and joint pain. *See* ECF No. 3-4 at 139–140; Pet'rs' Ex. 6 at 64–68; 213–17; ECF No. 4-4.

In September 2014, G.J.B. underwent an occupational therapy evaluation for fine motor delays. ECF No. 5-1 at 1. Ms. Bechel informed the therapist that G.J.B. was no longer taking anti-seizure medications but that a new neurologist was treating him for "eye flitting movements" and other abnormal behaviors. *Id.* Additional epilepsy monitoring was also performed in October 2014. Pet'rs' Ex. 4 at 1–77, ECF No. 3-5. At this time, Ms. Bechel reported that G.J.B. often

[3] "Hyperopia" is defined as "an error of refraction in which rays of light entering the eye parallel to the optic axis are brought to a focus behind the retina, as a result of the eyeball being too short from front to back." *Hyperopia*, Dorland's Medical Dictionary 881 (33 ed. 2020).

awoke at night unresponsive and displayed other manifestations of seizure activity, though a video EEG revealed no clinical evidence of seizure. *Id.* On December 15, 2014, a rheumatologist diagnosed G.J.B. with hypermobility and the possibility of Ehlers-Danlos syndrome. ECF No. 3-4 at 141–42.

In February 2015, G.J.B. began treatment with Dr. Thomas Dye at the Neurology Clinic at Cincinnati Children's Hospital. Pet'rs' Ex. 6 at 231–61, ECF No. 4-2. Dr. Dye assessed G.J.B. with "generalized epilepsy," and noted that it did not appear his seizure activity was as controlled as it could be. *Id.* at 236. Subsequent assessments of G.J.B. in the context of his schooling confirmed that he was largely functional and meeting his goals. Pet'rs' Ex. 17 at 75, ECF No. 12-3. By 2016, Dr. Dye deemed G.J.B.'s seizure activity to be well controlled, and subsequent rheumatologic follow-ups noted progress and improvement, despite ongoing joint pain. ECF No. 3-4 at 133–34. Medical records through 2017 indicate that G.J.B.'s seizures remained in good control during that time. *See, e.g.*, Pet'rs' Ex. 86 at 45, 71, 146, 198, 207, 280, ECF No. 59-4.

C. Procedural History

On July 26, 2016, Petitioners filed a petition seeking compensation under the Vaccine Act, 42 U.S.C. § 300aa-11(c)(1)(C)(ii). Pet. for Vaccine Comp. ¶ 1, ECF No. 1. Petitioners alleged that the administration of the DTaP, IPV, MMR, and VAR vaccines more likely than not caused G.J.B. to develop encephalopathy, epilepsy, seizures, delirium, confusion, altered mental state, and other injuries. *Id.* Special Master Roth was initially assigned to Petitioners' case.

On January 27, 2021, the case was reassigned to Chief Special Master Corcoran. Order, ECF No. 61. The Chief Special Master set a trial date for February 15–16, 2022. Order at 1, ECF No. 64. On November 2, 2021, Petitioners' former counsel asked for the trial date to be continued, as he intended to withdraw from the case. Pet'rs' Unopp. Mot. for a Continuance at 1, ECF No.

65. The Chief Special Master ultimately removed the case from the trial calendar and opted to resolve the case with a ruling on the record. Order at 1, ECF No. 68.

D. Expert Opinions

In addition to the referenced medical records, the Chief Special Master reviewed ten expert reports filed by four different experts: five reports filed by Petitioners' two experts and five reports filed by Respondent's two experts. *See generally* Pet'rs' Ex. 23, ECF No. 25-1; Pet'rs' Ex. 39, ECF No. 32-1; Pet'rs' Ex. 54, ECF No. 38-1; Pet'rs' Ex. 42, ECF No. 32-4; Pet'rs' Ex. 44, ECF No. 37-1; Resp't's Ex. A, ECF No. 28-1; Resp't's Ex. E, ECF No. 36-1; Resp't's Ex. G, ECF No. 47-1; Resp't's Ex. C, ECF No. 33-1; Resp't's Ex. F, ECF No. 44-1.

1. Petitioners' Expert Reports

Petitioners retained two experts: Dr. Marcel Kinsbourne, a pediatric neurologist and well-established researcher; and Dr. Vera Byers, an allergist and immunologist.[4] Pet'rs' Ex. 24, ECF No. 25-2; Entitlement Decision at 16, ECF No. 86.

In his first report, Dr. Kinsbourne reviewed G.J.B.'s medical history and confirmed G.J.B.'s epilepsy diagnosis. ECF No. 25-1 at 1–4. As to the cause of G.J.B.'s epilepsy, Dr. Kinsbourne concluded that the underlying wild measles virus, present in an attenuated form in the MMR vaccine, was known to be "neurotropic and neuropathic[,]" and that "[s]eizure onset within two weeks after MMR vaccination is a well-recognized adverse reaction to this vaccination." *Id.* at 4. Dr. Kinsbourne concluded that the onset of G.J.B.'s symptoms within five days of vaccination, occurred within a medically reasonable temporal interval after vaccination to be associated with a vaccine cause. *Id.* at 4, 6.

[4] Dr. Byers did not offer a CV in this case. The Chief Special Master recited her credentials from another case. *See L.M. v. Sec'y of Health & Hum. Servs.*, No. 14-714V, 2019 WL 4072130, at *10 (Fed. Cl. Spec. Mstr. July 23, 2019).

Dr. Kinsbourne also filed two supplemental reports that largely focused on addressing the issue of whether afebrile seizures could be caused by vaccines. Dr. Kinsbourne cited a study that observed a small but significant number of afebrile seizure events post-vaccination. ECF No. 32-1 at 1 (citing N. Verbeek et al., *Etiologies for Seizures Around the Time of Vaccination*, 134 Pediatrics 4:658, 659–60 (2014), Pet'rs' Ex. 72, ECF No. 42-12 ("Verbeek")). From data in another study, he inferred that, while 43 vaccinated children who later experienced encephalopathy had been febrile, five children in the study had been afebrile when the encephalopathy occurred. *Id.* (citing R. Weibel et al., *Acute Encephalopathy Followed by Permanent Brain Injury or Death Associated with Further Attenuated Measles Vaccines: A Review of Claims Submitted to the National Vaccine Injury Compensation Program*, 101 Pediatrics 3:383, 385 (1998), Pet'rs' Ex. 70, ECF No. 42-10 ("Weibel")). Other studies cited by Dr. Kinsbourne observed an association between influenza, adenovirus, rotavirus, or RSV infections and afebrile seizures, ECF No. 38-1 at 3 (citing B. Chung and V. Wong, *Relationship Between Five Common Viruses and Febrile Seizure in Children*, 92 Arch. Dis. Child 589 (2007), Pet'rs' Ex. 78, ECF No. 42-18 ("Chung and Wong")), or supported the contention that a number of infections could likely provoke afebrile seizures, *id.* at 2 (citing W. Lee and H. Ong, *Afebrile Seizures Associated with Minor Infections: Comparison with Febrile Seizures and Unprovoked Seizures*, 31 Pediatric Neurology 3:157 (2004), Pet'rs' Ex. 74, ECF No. 42-14 ("Lee and Ong")). Dr. Kinsbourne concluded that the association between febrile seizures and vaccination was the product of "two independent effects," *i.e.*, the generation of fever due to vaccine-induced upregulation of certain proinflammatory cytokines, and seizure propagation involving cytokines generally. *Id.* In an attempt to decouple fever from seizures, Dr. Kinsbourne explained that the two processes do not always occur simultaneously and that a fever could follow a seizure. *Id.* (citing C. Waruiru and R. Appleton,

Febrile Seizures: An Update, 89 Arch. Dis. Child 751 (2004), Pet'rs' Ex. 84, ECF No. 42-43 ("Waruiru")).

Dr. Byers attempted to further explain that pro-inflammatory cytokines can cause fevers and seizures independently. ECF No. 32-4 at 2–4; ECF No. 37-1 at 1–3. Identifying IL-1β as the key cytokine associated with both processes, Dr. Byers pointed to research suggesting that IL-1β could play a dual role, *i.e.*, the cytokine could cause fever, but it also could lower the seizure threshold and thus cause seizures even in the absence of fever. ECF No. 32-4 at 2. As explanation for this duality, Dr. Byers argued that individuals suffering from febrile versus afebrile seizures would have distinguishable "cytokine profiles." *Id.* at 2–3. Further, Dr. Byers argued that that cytokines produced in reaction to vaccination could have the same effect as a mild infection; thus, a vaccine-induced afebrile seizure would be comparable to a "provoked" seizure caused by naturally occurring infection. ECF No. 37-1 at 2. As applied to the instant case, Dr. Byers contended that the evidence of leg swelling and headaches experienced by G.J.B. after vaccination was a result of a pro-inflammatory cytokine response sufficient to provoke an afebrile seizure. *Id.*

2. Respondent's Expert Reports

Respondent also retained two experts: Dr. Shlomo Shinnar, a pediatric neurologist with expertise in the treatment of epilepsy; and Dr. Andrew MacGinnitie, an immunologist who is the Clinical Director for the Division of Immunology at Boston Children's Hospital and an Associate Professor of Pediatrics at Harvard Medical School. Resp't's Ex. B, ECF No. 28-13; Resp't's Ex. D, ECF No. 34-6.

Dr. Shinnar reviewed G.J.B.'s medical history, with additional emphasis on the pre-vaccination evidence of G.J.B.'s "speech deficit" and the circumstantial evidence of the family's neurologic issues. ECF No. 28-1 at 3–5. He agreed with G.J.B.'s epilepsy diagnosis and opined

that a diagnosis of epilepsy with an "unknown cause" best captured G.J.B.'s clinical presentation; indeed, most cases of epilepsy lacked an identifying cause in his experience. *Id.* at 6. Dr. Shinnar then spent the bulk of his reports responding to contentions made by Drs. Kinsbourne and Byers and attacking their theory's strength and reliability. *See id.* at 6–7; ECF No. 36-1 at 4–7; ECF No. 47-1 at 5–7. A key point made by Dr. Shinnar was the lack of accepted medical understanding supporting a causal connection between vaccines and afebrile seizures. ECF No. 28-1 at 5; ECF No. 36-1 at 4; ECF No. 47-1 at 6. For example, Dr. Shinnar argued that the 2012 Institute of Medicine Report, which reviewed the then-existing literature on the topic, is authoritative on the issue and did not make any conclusive findings regarding a causal connection between MMR vaccines and afebrile seizures. ECF No. 28-1 at 6–7; ECF No. 36-1 at 4; ECF No. 47-1 at 6 (citing *Adverse Effects of Vaccines: Evidence and Causality* 133–37 (K. Stratton et al., eds., 2011), Pet'r's Ex. A Tab 6, ECF No. 28-7 ("Stratton II")). Regarding the DTaP vaccine, Dr. Shinnar referenced a retrospective observational study disputing a reliable association between the vaccine and both febrile and afebrile seizures. ECF No. 28-1 at 5 (citing W. Huang et al., *Lack of Association Between Acellular Pertussis Vaccine and Seizures in Early Childhood*, 126 Pediatrics 263 (2010), Resp't's Ex. A Tab 7, ECF No. 28-8 ("Huang")). Further, Dr. Shinnar reviewed other pieces of literature cited by Dr. Kinsbourne and found them to be greatly outdated or lacking reliable methodologic controls. *Id.*

Responding to Dr. Byers's contentions, Dr. Shinnar disagreed with her assertion that IL-1β is involved in both febrile and afebrile seizures and thus they share a common immunologic mechanism. ECF No. 36-1 at 5; ECF No. 47-1 at 6–7. Dr. Shinnar supported his position by pointing out, for example, that the study cited by Dr. Byers for a shared mechanism of action in febrile and afebrile seizures had in fact only discussed the association between IL-1β and *febrile*

seizures. ECF No. 47-1 at 6. Moreover, another study cited by Dr. Byers, Stratton II, only reliably observed an association between MMR vaccines and *febrile* seizures, thus Dr. Shinnar concluded that any application to afebrile seizures should be limited. ECF No. 28-1 at 5. In further critique of Dr. Byers's conclusions, Dr. Shinnar noted that the Verbeek study had identified only three out of 990 children who experienced post-MMR vaccine afebrile seizures, a very small sample size, and two of these afebrile children possessed a family history of afebrile seizures. ECF No. 36-1 at 4. Further limiting the study's persuasive value, Dr. Shinnar pointed out that the Verbeek study also involved children far younger than G.J.B. *Id.*

In short response to Dr. Kinsbourne, Dr. MacGinnitie disagreed with the possibility that the small amount of wild virus present in vaccines could cause afebrile seizures. ECF No. 33-1 at 7–8. He argued that of the many kinds of "immune challenges" individuals confront daily, the risk posed by vaccines was far outweighed by wild infections, and he deemed vaccination "a minor immune stimulus" generally unlikely to provoke injury. *Id*. Turning to the conclusions made by Dr. Byers, Dr. MacGinnitie argued that accepted medical science associates inflammatory cytokines only with *febrile* seizures, and those same cytokines have not been shown to cause afebrile seizures or increase due to vaccination in sufficient amounts to be harmful. *Id.* at 3–6. In particular, Dr. MacGinnitie noted that Dr. Byers's reports had referenced only a few articles dealing with afebrile seizures, and the articles were either specific to infections or did not offer any discussion of what the necessary cytokine levels would be to produce seizure. *Id.* at 4 (analyzing T. Zhang et al., *Are Afebrile Seizures Associated with Minor Infections a Single Seizure Category? A Hospital-Based Prospective Cohort Study on Outcomes of First Afebrile Seizure in Early Childhood*, 55 Epilepsia 7:1001 (2014), Pet'rs' Ex. 53, ECF No. 37-10 (Zhang); Lee and Ong). Instead, Dr. MacGinnitie cited to a study that showed specific cytokine levels were *not*

increased in afebrile seizure patients, *id.* at 4–5 (citing J. Choi et al., *Increased Levels of HMGB1 and Pro-Inflammatory Cytokines in Children with Febrile Seizures*, 8 J. Neuroinflamm. 135 (2011), Resp't's Ex. C Tab 5, ECF No. 33-6 ("Choi")), and another study provided strong epidemiological evidence against an association between DTP[5] and MMR vaccinations and afebrile seizures. ECF No. 44-1 at 3 (citing Barlow et al., *The Risk of Seizures After Receipt of Whole-Cell Pertussis or Measles, Mumps, and Rubella Vaccine*, 345 N. Engl. J. Med. 9:656 (2001), Resp't's Ex. F Tab 1, ECF No. 44-2 ("Barlow")). Alternatively, Dr. MacGinnitie contended that increased levels of cytokines in individuals suffering from seizures could be the result of seizure activity rather than the cause. ECF No. 33-1 at 4.

E. The Entitlement Decision

On May 22, 2023, the Chief Special Master issued his Entitlement Decision, denying Petitioners' claims in full. ECF No. 86 at 2. The Chief Special Master held that Petitioners had not met their burden of showing that G.J.B.'s injuries were caused by the DTaP, IPV, MMR, and VAR vaccines based on the three-prong causation test set forth in *Althen v. Secretary of Health and Human Services*, 418 F.3d 1274 (Fed. Cir. 2005). *Id.* at 40–47. Regarding the first prong of the *Althen* test, which requires a medical theory causally connecting the vaccination and the injury, the Chief Special Master found Petitioners did not establish that any of the vaccines G.J.B. received can cause afebrile seizures. *Id.* at 40. As an initial matter, the Chief Special Master rejected Petitioners' threshold argument that the first *Althen* prong is subject to a plausibility standard as being "simply mistaken." *Id.* He explained that "the relevant standard for the first prong is preponderance, even though Petitioners may *satisfy* that prong with a wide array of circumstantial

[5] "DTP" is a whole-cell pertussis formulation of the diphtheria-tetanus-pertussis vaccine.

evidence (and thus cannot be faulted for not affirmatively offering *any one particular kind* of evidence, such as a reliable epidemiologic study)." *Id.* (emphasis in original).

The Chief Special Master then addressed the two medical theories of causation posited by Petitioners' experts, which are that: (a) pro-inflammatory cytokines associated with febrile seizures can also likely cause afebrile seizures, and (b) cytokines stimulated/produced by vaccination reach levels comparable to what is produced in a reaction to a wild infection sufficient to cause an afebrile seizure. *Id.* at 41–44. The Chief Special Master noted that "[t]he general gist of Petitioners' causation theory—that cytokines generated in association with vaccination, and that prompt fever, could theoretically cause afebrile seizures in a susceptible individual—had a baseline level of plausibility." *Id.* at 41. However, he found that Petitioners' theory over-relied on how vaccines are generally understood to function (*i.e.*, the initial response to vaccination can cause an upregulation of many proinflammatory cytokines that can in turn produce fever in the body thereby triggering a *febrile* seizure) without offering evidence supporting the conclusion that vaccination can produce cytokines in sufficient amounts, and of the right type, to cause *afebrile* seizures. *Id.* at 41–42. Because they did not demonstrate that the vaccines received by G.J.B. could have kicked off the entire pathogenic pathway posited by their experts, the Chief Special Master found that Petitioners failed to meet *Althen*'s first prong. *Id.* at 44.

Regarding the second *Althen* prong, which requires a logical sequence of cause and effect showing that the vaccination was the reason for the injury, the Chief Special Master found that G.J.B.'s neurologic treaters did not endorse vaccine causality and the record lacked evidence of a contemporaneous treater speculating that vaccination had triggered G.J.B.'s seizures. *Id.* at 45. The Chief Special Master recognized record support for the conclusion that G.J.B. experienced some post-vaccination inflammation, followed by stuttering and language activity that later

treaters viewed as reflective of seizure activity. *Id.* Even so, he found that Petitioners' experts did not establish that any of G.J.B.'s initial vaccine malaise was caused by the same cytokine response that would usually cause fever (but did not in G.J.B.) under a causation theory of aberrant cytokine impact. *Id.* Because the record did not establish that the vaccines produced any fever in G.J.B., or that his fevers were febrile, the Chief Special Master concluded there was an "evidentiary disconnect between the fact of some possible initial vaccine reaction and the proposed afebrile mechanism for how G.J.B.'s seizures would later occur." *Id.* (internal quotations omitted). The Chief Special Master reasoned that, other than witness testimony about G.J.B.'s post-vaccination malaise, the record did not contain any independent evidence supporting Petitioners' experts' posited theory of causation. *Id.* According to the Chief Special Master, to convert the mere temporal association of G.J.B.'s post-vaccination seizures into proof of causation would be an endorsement of *post hoc ergo propter hoc* reasoning. *Id.* (citing *Galindo v. Sec'y of Health & Hum. Servs.*, No. 16-203V, 2019 WL 2419552, at *20 (Fed. Cl. Spec. Mstr. May 14, 2019).

While the Chief Special Master declined to make an explicit finding as to the cause of G.J.B.'s condition, he endorsed Dr. Shinnar's "compelling interpretation of G.J.B.'s history" and conclusion that G.J.B.'s seizures were of idiopathic origin as the "best understanding of the facts." *Id.* at 46. Explaining that Dr. Shinnar "rooted his opinion in persuasive evidence suggesting [] how most epilepsy experts would read the medical records" in G.J.B.'s case, the Chief Special Master gave Dr. Shinnar's construction of the medical records more weight than that of Petitioners' experts and found Petitioners did not produce preponderant evidence to satisfy *Althen*'s second prong. *Id.* at 47.

Regarding the third *Althen* prong, which requires a showing of a proximate temporal relationship between vaccination and injury, the Chief Special Master found preponderant

evidence to establish that G.J.B.'s post-vaccination episodes of language issues and stuttering, which were interpreted by initial treaters as the likely product of seizure activity, had manifested within about five days of vaccination. *Id.* at 46. As such, he found Petitioners satisfied their *Althen* prong-three burden. *Id.* Nonetheless, their failure to meet the first two prongs warranted denial of compensation. *Id.*

F. The Motion for Review

On June 21, 2023, Petitioners timely filed a Motion for Review of the Entitlement Decision. Pet'rs' Mot. for Rev. at 1, ECF No. 90. Petitioners ask the Court to set aside the Chief Special Master's findings of fact and conclusions of law as arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. *Id.* Specifically, Petitioners claim that the Chief Special Master impermissibly heightened the burden of proof under the first *Althen* prong by dismissing relevant evidence of biologic plausibility and requiring direct proof and confirmation of their causal theory. Mem. of Objs. in Supp. of Pet'rs' Mot. for Rev. at 3, ECF No. 90-1. Petitioners also claim the Chief Special Master erred by finding that an unknown or idiopathic explanation of G.J.B.'s condition constituted a "factor unrelated" to the administration of the vaccines, which pursuant to the Vaccine Act cannot defeat Petitioners' right to recovery. *Id.*

On July 20, 2023, Respondent filed its response to Petitioners' Motion for Review, arguing that the Chief Special Master: (1) applied the correct legal standard when evaluating whether Petitioners had preponderantly established the first *Althen* prong; (2) made his factual findings under *Althen* prong one based on the evidence as a whole using the correct legal standard, which he rationally explained and supported with citations to the record; and (3) properly adhered to applicable law when evaluating the evidence of a logical sequence of cause and effect under *Althen*

prong two. Resp't's Resp. to Pet'rs' Mot. for Rev. at 12–22, ECF No. 92. The Court heard oral argument on October 5, 2023.

II. LEGAL STANDARD

A. The Court's Standard of Review

This Court has jurisdiction to review a special master's entitlement decision upon the timely request of either party. 42 U.S.C. § 300aa-12(e)(2). Under the Vaccine Act, a court deciding a motion for review may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
> (C) remand the petition to the special master for further action in accordance with the court's direction.

Id. §§ 300aa-12(e)(2)(A)–(C); *accord* Vaccine Rule 27(c). The standards of review set forth in 42 U.S.C. § 300aa-12(e)(2)(B) "vary in application as well as degree of deference" as each "standard applies to a different aspect of the judgment." *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). The special master's factual findings are reviewed under an arbitrary and capricious standard. *Id.* The scope of review is thus limited and highly deferential. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *see Munn*, 970 F.2d at 870 (review of a special master's factual findings is "well understood to be the most deferential possible" (citations omitted)). "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines ex rel. Sevier v. Sec'y of Dept. of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). When the court's review of a special master's decision involves statutory construction or other legal issues, it applies the "not

in accordance with law" standard. *Id.* at 1527. The third standard of review, abuse of discretion, is applicable when the special master excludes evidence or otherwise limits the record upon which he relies. *See Munn*, 970 F.2d at 870 n.10.

"[S]pecial masters have broad discretion to weigh evidence and make factual determinations." *Dougherty v. Sec'y of Health & Hum. Servs.*, 141 Fed. Cl. 223, 229 (2018). When reviewing the special master's factual findings, the court does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). The court should not "second guess the Special Master[']s fact-intensive conclusions particularly in cases in which the medical evidence of causation is in dispute." *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (quotations omitted) (quoting *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)).

B. The Standard of Causation in Vaccine Cases

A petitioner may establish that a vaccine caused an alleged injury in one of two ways. 42 U.S.C. § 300aa-11(c); *see Munn*, 970 F.2d at 865. First, a petitioner who has received a vaccine listed on the Act's Vaccine Injury Table ("Table") may recover for any resulting illness, disability, injury, or condition that is also listed on the Table, or a significant aggravation thereof. 42 U.S.C. §§ 300aa-11(c)(1)(C)(i), 300aa-14; *see Althen*, 418 F.3d at 1278 (describing a "Table injury"). Second, a petitioner who has received a vaccine listed on the Table, but whose vaccine-related injury does not meet Table requirements, may recover under an "off-Table" theory. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A).

Under an off-Table theory, a petitioner may make a prima facie case of entitlement to compensation by showing, by a preponderance of evidence, that a Table vaccine actually caused the petitioner to sustain an illness, disability, injury, or condition which is not listed on the Table, or that first appeared outside the time limits set by the Table. *Id.* § 300aa-11(c)(1)(C)(ii); *see Pafford v Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). For a petitioner to successfully recover for an off-Table claim, he or she must establish causation-in-fact. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1); *Pafford*, 451 F.3d at 1355. This requires "preponderant evidence both that [the] vaccination[] [was] a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford*, 451 F.3d at 1355 (citing *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). The vaccination "must be a 'substantial factor'" in bringing about the injury, but "it need not be the sole factor or even the predominant factor." *Id.* at 1357 (quoting *Shyface*, 165 F.3d at 1352–53).

To make the showing that "the vaccination brought about [the] injury," a petitioner must show: "(1) a medical theory causally linking the vaccine and the injury; (2) a logical sequence of cause and effect showing the vaccine was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. "[N]either a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation" under the three-factor test. *Id.* (citing *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992)). Nor may the special master make a finding of causation based on the claims of a petitioner alone, which are not substantiated by medical records

or by medical opinion. *See* 42 U.S.C. § 300aa-13(a)(1). Thus, the presentation of medical records or medical opinion supporting a claim is a prerequisite to recovery. *Id.*

In off-Table cases, petitioners bear the burden to prove actual causation by a preponderance of evidence. *Althen*, 418 F.3d at 1278; *see* 42 U.S.C. § 300aa-11(c)(1)(A). The preponderant-evidence standard requires that a petitioner demonstrate proof "by a simple preponderance, of 'more probable than not' causation." *Althen*, 418 F.3d at 1279 (citing *Hellebrand v. Sec'y of Health & Hum. Servs.*, 999 F.2d 1565, 1572–73 (Fed. Cir. 1993)). This standard "simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension T. for S. Cal.*, 508 U.S. 602, 622 (1993)). In evaluating the evidence put forth to meet the preponderance standard, the special master has discretion to determine the relative weight of the evidence presented, including contemporaneous medical records and oral testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *see also Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1355, 1368 (Fed. Cir. 2012).

If a petitioner presents adequate evidence on the three essential aspects of causation, and thus makes a prima facie case for liability, the burden shifts to the Government to prove, by a preponderance of evidence, an alternate cause of the alleged injury. *Althen*, 418 F.3d at 1278; *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008).

III. DISCUSSION

Petitioners' motion raises two objections to the Chief Special Master's decision. They first contend that the Chief Special Master applied the incorrect legal standard in his evaluation of *Althen* prong one, both to what he required them to prove for general causation and how he required

them to prove it. ECF No. 90-1 at 3. Second, Petitioners contend that the Chief Special Master applied the incorrect legal standard to his evaluation of *Althen* prong two. *Id.* Having considered the arguments and record, the Court rejects both objections. Regarding the first *Althen* prong, the Chief Special Master applied the correct legal standard to assess their medical theory of general causation, even though he committed harmless error in mischaracterizing Petitioners' plausibility argument. Regarding the second *Althen* prong, the Chief Special Master committed no legal error by considering all relevant evidence in the record to determine whether Petitioners had established specific causation, including evidence of an unknown or idiopathic explanation of G.J.B.'s condition. Accordingly, the Chief Special Master's decision is upheld.

A. The Chief Special Master Appropriately Evaluated the First *Althen* Prong.

The Chief Special Master correctly explained that the first *Althen* prong requires a theory of general causation based on a sound and reliable medical or scientific explanation demonstrating that the vaccine at issue can cause the type of injury alleged, and that this theory must be supported by preponderant evidence. As such, even though the Chief Special Master mischaracterized Petitioners' first objection as one taking issue with the evidentiary standard applicable to *Althen* prong one, this error was harmless because he applied the proper legal standard. Further, the Chief Special Master did not require direct evidence from medical literature to support Petitioners' medical theory, but rather properly weighed the probative value of the literature offered by both parties. Accordingly, the Chief Special Master did not commit legal error in his evaluation of the first *Althen* prong.

1. The Chief Special Master Applied the Correct Legal Standard but Committed Harmless Error in Mischaracterizing Petitioners' Plausibility Argument.

Petitioners allege that the Chief Special Master erred in his evaluation of the first *Althen* prong by using the incorrect legal standard to assess their medical theory of general causation.

ECF No. 90-1 at 10. According to Petitioners, the Chief Special Master rejected the "traditional concept of 'biological plausibility' and instead required Petitioner[s] to provide direct proof and confirmation of the[ir] theory." *Id.* Respondent disagrees, arguing that the Chief Special Master "correctly articulated the applicable preponderance legal standard." ECF No. 92 at 13. This response, however, misses the mark.

Petitioners' objection does not relate to the evidentiary standard of proof that the Chief Special Master applied to *Althen* prong one—*i.e.*, the quantum of evidence that Petitioners were required to present to prevail on that factor. It is instead an objection to *what* they had to show, and *how* they could make that showing, to meet their burden—*i.e.*, what Petitioners were required to establish through their evidence to prevail. While the two standards are often intertwined in the case law, Respondent ignores or, at best, conflates these distinct legal concepts. Even when properly disentangled, however, Petitioners' claim fails because the Chief Special Master correctly articulated the legal standard for *Althen* prong one and his similar mischaracterization of Petitioners' argument was harmless error.

Althen prong one requires a petitioner to show "a medical theory causally connecting the vaccination and the injury." *Althen*, 418 F.3d at 1278. In simpler terms, "a petitioner must demonstrate that the vaccine at issue *can cause* the injury alleged." *Greene v. Sec'y of Health & Hum. Servs.*, 146 Fed. Cl. 655, 663 (2020) (emphasis added) (citing *Pafford*, 451 F.3d at 1355–56). As an initial matter, the parties do not dispute that it was Petitioners' burden to establish their prima facie case by a preponderance of evidence—nor could such principle be reasonably disputed. The standard of proof in the Vaccine Program is a statutory requirement. *See* 42 U.S.C. § 300aa-13(a)(1)(A) ("Compensation shall be awarded . . . if . . . the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition.")). In interpreting the

statute, the Federal Circuit has consistently and unequivocally applied a preponderance standard to the petitioner's overall burden of proof. *See, e.g.*, *Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1102 (Fed. Cir. 1996); *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1307 (Fed. Cir. 1999); *Guillory v. Sec'y of Health & Hum. Servs.*, 104 F. App'x 712, 712–13 (Fed. Cir. 2004); *de Bazan*, 539 F.3d at 1351–52: *Broekelschen*, 618 F.3d at 1341–42; *Lasnetski v. Sec'y of Health & Hum. Servs.*, 696 F. App'x 497, 503 (Fed. Cir. 2017); *Wright v. Sec'y of Health & Hum. Servs.*, 22 F.4th 999, 1001 (Fed. Cir. 2022). While the Federal Circuit adjusted the requirements of the causation test in *Althen*, the evidentiary standard for a petitioner's overall burden remained unchanged. *See Althen*, 418 F.3d at 1278 ("[The] burden is to show by preponderant evidence that the vaccination brought about injury."). It has since held that the preponderance standard of proof also applies to the petitioner's burden under each individual *Althen* prong, including prong one. *See Oliver v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010) ("To demonstrate causation, the petitioner's 'burden is to show by preponderant evidence' *each* of the requirements set forth in *Althen*[.]") (emphasis added)); *Olson v. Sec'y of Health & Hum. Servs.*, 758 F. App'x 919, 922 (Fed. Cir. 2018) (citing *Oliver*, 618 F.3d at 1350); *see also Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) ("Petitioners failed to meet their burden to prove by a preponderance of evidence that vaccinations can and did cause or contribute to J.B.'s death from SIDS.").

Exactly *what* a petitioner must show by preponderant evidence to prevail under *Althen* prong one is also established through a consistent line of precedent. To meet the first prong, the Federal Circuit has repeatedly held that a petitioner's theory of general causation must be established by a "reputable," "sound[,] and reliable" medical theory. *Knudsen v. Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994); *see, e.g.*, *Althen*, 418 F.3d at 1278 ("A persuasive

medical theory is demonstrated by . . . a reputable medical or scientific explanation." (internal quotations omitted) (citing *Grant*, 956 F.2d at 1148)); *Andreu ex rel. Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379–80 (Fed. Cir. 2009) ("*Althen* makes clear that a claimant's theory of causation must be supported by a 'reputable medical or scientific explanation.'"); *Broekelschen*, 618 F.3d at 1352 (affirming special master's decision where petitioner had not provided a "reliable medical or scientific explanation" sufficient to prove its medical theory linking the flu vaccine to anterior spinal artery syndrome); *Boatmon*, 941 F.3d at 1359 (describing the "'reputable,' 'sound and reliable' standard" as the correct standard for *Althen* prong one).

To be successful, a medical theory need not identify a "specific biological mechanism[]" proving the link between the vaccine and the injury. *Knudsen*, 35 F.3d at 549 (explaining that "[c]ausation can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms" involved). Nor does the medical theory need to be medically or scientifically certain. *See Broekelschen*, 618 F.3d at 1345. A petitioner is likewise not required to show that the theory is generally accepted, and he may demonstrate his theory without resort to medical literature or epidemiological studies. *See Andreu*, 569 F.3d at 1378–79 (citing *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1320, 1325–26 (Fed. Cir. 2006)).

But the medical theory must nonetheless be sound and reliable for a petitioner to prevail. Thus, a special master's evaluation of *Althen*'s first prong is both a fact-specific inquiry and an exercise of his or her judgment to determine the relative weight of the evidence presented "in a field bereft of complete and direct proof of how vaccines affect the human body." *Althen*, 418 F.3d at 1280; *see Hodges*, 9 F.3d at 967 ("[T]he factfinder must decide the reliability, consistency, and probative value of the scientific evidence, with the guidance of scientific opinion.").

The crux of Petitioners' argument centers on whether preponderant proof of a medically plausible theory is enough to satisfy *Althen* prong one. ECF No. 90-1 at 14. According to Petitioners, prior to *Moberly*, "[t]he standard for articulating a medical theory in expert testimony, as restated across the first 25 years of Federal Circuit cases addressing this question, is 'medical plausibility.'" *Id.* at 10. There is some merit to that argument. While recognizing that the medical theory must be sound and reliable, the Federal Circuit in *Althen* described prong one as "proof of medical plausibility." *Althen*, 418 F.3d at 1281 (rejecting two factors of the prior *Stevens* causation test but noting that the remaining *Stevens* factors, including medical plausibility, are "merely a recitation of this court's well-established precedent"). In other cases, it has also held or otherwise explained that "plausible" medical theories of general causation are sufficient under *Althen*'s first prong. *See, e.g.*, *Andreu*, 569 F.3d at 1382 (concluding that petitioner satisfied *Althen* by offering, among other evidence, a biologically and scientifically plausible theory of causation); *Hibbard*, 698 F.3d at 1365 (explaining that petitioner "had to show both the medical plausibility of her theory of causation and that she suffered an injury consistent with that theory of causation"); *see also Veryzer v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 344, 352 (2011) (explaining that "plausible causation relates to evaluation of *Althen*'s first prong, which is satisfied by a biologically plausible theory" (quotation marks omitted)), *aff'd sub nom. Veryzer v. United States*, 475 F. App'x 765 (Fed. Cir. 2012); *Trollinger v. Sec'y of Health & Hum. Servs.*, 167 Fed. Cl. 127, 138 (2023) (reading *Andreu* as holding that "a theory demonstrated to be 'biologically plausible' by preponderant evidence" satisfies *Althen* prong one (emphasis omitted)).

Petitioners claim that the Federal Circuit's decision in *Moberly* introduced some confusion as to the use of a plausibility standard vis-à-vis *Althen* prong one. ECF No. 90-1 at 11. In *Moberly*, the Federal Circuit held that "proof of a 'plausible' or 'possible' causal link between the vaccine

and the injury . . . is not the statutory standard." 592 F.3d at 1322. As Petitioners correctly note, read in the proper context, *Moberly* criticized the use of "plausibility" as the evidentiary standard for proving causation-in-fact across all three *Althen* prongs. *Id.* It did not hold that a petitioner's proposed medical theory under *Althen* prong one must be more than plausible.[6] *See Contreras v. Sec'y of Health & Hum. Servs.*, 121 Fed. Cl. 230, 245 (2015) ("The discussion of plausibility in *Moberly* does not focus on *Althen* prong one specifically, and has no relevance to the question of whether a plausible medical theory satisfies *Althen* prong one."), *vacated on other grounds*, 844 F.3d 1363 (Fed. Cir. 2017). Rather, *Moberly* reaffirmed that the "traditional 'more likely than not' standard"—*i.e.*, the preponderance evidentiary standard—applies to the overall question of whether the vaccine caused the injury in the case of the petitioner at bar. 592 F.3d at 1322.

Although *Moberly* rejected plausibility as the overall evidentiary standard of proof for causation, subsequent cases have relied on *Moberly* to reject the notion that a medically plausible theory meets the legal standard for *Althen*'s first prong. In *Boatmon*, for example, the Federal Circuit held that the special master "deviated from the correct 'reputable,' 'sound and reliable' [*Althen* prong one] standard and articulated a lower 'reasonable' standard," 941 F.3d at 1359, when, for example, the special master found the petitioner's expert presented only a "'*plausible mechanism*'" whereby the vaccine could indirectly cause death in infants, *id.* at 1360 (emphasis in original); *see also id.* (noting that the special master found the mechanism underlying the petitioner's theory "*scientifically-plausible*" or "*plausible*" (emphasis in original)). *Boatmon* cited to *Moberly* and a second case, *Lalonde v. Secretary of Health and Human Services*, 746 F.3d 1334

[6] Indeed, *Moberly* acknowledged that the same theory of general causation at issue in the case was previously credited in *Andreu* as being biologically plausible. 592 F.3d at 1325. It did not disagree with *Andreu*'s holding that a plausible theory could satisfy prong one; instead, it distinguished *Andreu* because the Government's expert in *Moberly*, unlike in *Andreu*, did not concede the biological plausibility of the theory. *Id.*

(Fed. Cir. 2014), to reject this "plausible" theory as sufficient to establish causation under *Althen*. *Boatmon*, 941 F.3d at 1360.

However, neither *Moberly* nor *LaLonde* addressed plausibility in the context of a prong one showing.[7] *See Moberly*, 592 F.3d at 1322; *LaLonde*, 746 F.3d at 1339. To the extent *Boatmon* held that preponderant proof of a plausible medical theory established by a sound and reliable medical or scientific explanation is insufficient to prevail on *Althen* prong one, it conflicts with prior precedential decisions. *See Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988).

More recently, in *Kottenstette v. Secretary of Health and Human Services*, the Federal Circuit reversed the Court of Federal Claims for applying *Boatmon* to set aside a special master's decision, where the lower court equated the special master's "biologic credibility" standard for *Althen* prong one to "the 'plausible' or 'reasonable' standard that the Federal Circuit rejected in *Boatmon*." 861 F. App'x 433, 440 (Fed. Cir. 2021) (quoting *Kottenstette v. Sec'y of Health & Hum. Servs.*, No. 15-1016V, 2020 WL 953484, at *3 (Fed. Cl. Feb. 12, 2020)). The Court held that "biologic credibility" did not set a new lower standard and that the special master correctly recited the holding "in several precedential cases[,] that proof of causation does not 'require identification and proof of specific biological mechanisms[.]" *Id.* at 440–41 (quoting *Knudsen*, 35 F.3d at 549); *see id.* at 441 (citing *Simanski v. Sec'y of Health & Hum. Servs.*, 671 F.3d 1368, 1384 (Fed. Cir. 2012) (noting in parenthetical the requirement of a sound and reliable medical theory of

[7] Importantly, in explaining the petitioner's burden to provide "a reputable and scientific explanation of causation," *LaLonde* cited to *Hibbard*, which described the petitioner's burden as requiring both a *medically plausible* theory of causation and a showing that the injury was consistent with that theory. *LaLonde*, 746 F.3d at 1340 (citing *Hibbard*, 698 F.3d at 1365).

causation). According to *Kottenstette*, "*Boatmon* did not, and indeed, could not, overrule these previous articulations of the standard for causation." *Id.* at 441.

Ultimately, the Court need not wade further into the morass of caselaw discussing the *Althen* prong one showing. The exact issue presented here is now before the Federal Circuit on appeal, and the much-needed clarity that the Court provides will be binding on both this Court and the Office of Special Masters. *See Howard v. Sec'y of Health & Hum. Servs.*, 21-1816 (Fed. Cir. filed Apr. 25, 2023). For purposes of resolving Petitioners' motion, the Court finds that the Chief Special Master correctly identified and applied the legal standard for the first *Althen* prong one, finding that Petitioners had not sufficiently established a medical theory of general causation based on a reliable medical or scientific explanation.

To begin, the Chief Special Master correctly explained that "[u]nder *Althen* prong one, petitioners must provide a 'reputable medical theory[]" demonstrating that the vaccine received *can* cause the type of injury alleged. ECF No. 86 at 33 (emphasis in original) (citing *Pafford*, 451 F.3d at 1355–56). Consistent with precedent, he further explained that "[t]o satisfy this prong, a petitioner's theory must be based on a 'sound and reliable medical or scientific explanation.'" *Id.* (internal citations omitted). And like the special master in *Kottenstette*, he accurately noted that proof of causation does not require, among other things, demonstration of a specific biological mechanism. *Id.* This is the correct legal standard for *Althen* prong one, as evidenced by the overwhelmingly consistent precedent; the Chief Special Master did not err. The Chief Special Master likewise did not err in identifying the proper evidentiary standard applicable to prong one—*i.e.*, preponderant evidence. *Id.* at 34, 40.

On the issue of plausibility, however, the Chief Special Master, like the Government here, mischaracterized Petitioners' objection as a challenge to the evidentiary standard. *See id.* at 30,

40–41. Additionally, the Chief Special Master's statement that the Federal Circuit has "consistently rejected" the contention that a petitioner can meet his prong one burden by establishing a scientifically or medically plausible general causation theory is not entirely accurate. *Id.* at 34. As exemplified by the citation immediately preceding this comment, both the Court of Federal Claims and the Federal Circuit have acknowledged that a showing of plausibility "in many cases *may* be enough to satisfy *Althen* prong one." *Contreras*, 121 Fed. Cl. at 245 (emphasis in original) (citing *Hibbard*, 698 F.3d at 1365); *see, e.g.*, *Andreu*, 569 F.3d at 1382; *but see Boatmon*, 941 F.3d at 1359–60. Even so, such errors were harmless. As the Chief Special Master correctly concluded, and as is undisputed in this case, preponderance is the appropriate evidentiary standard of proof for *Althen*'s first prong.

The Chief Special Master then evaluated Petitioners' "can cause" theory, finding it deficient in several respects. ECF No. 86 at 41. His consideration properly focused on the soundness and reliability of Petitioners' medical theory of general causation. As more thoroughly discussed below, the Chief Special Master found that Petitioners over-relied on how vaccines are generally understood to function, noting that more than "*reasoned* speculation" was necessary to prove up Petitioners' theory. *Id.* (emphasis in original) (holding that a "vaccine's anticipated stimulation of cytokine production is not enough of a basis for causation if not also connected to preponderant evidence that this expected immune response can be aberrant in some manner"). The Chief Special Master found that reliable proof connecting Petitioners' cytokines theory, and the specific vaccines at issue, to afebrile seizures was lacking. *Id.* at 42–43 (taking issue with Petitioners' over-reliance on research pertaining to febrile seizure, other kinds of injuries, and other types of vaccines not at issue), and noting that Petitioners' conclusions often derived from evidence of temporal associations between seizure onset and vaccines taken from larger studies that either

contradicted or did not reliably support a relationship between vaccines and afebrile seizure). Moreover, he concluded that Petitioners did not offer sufficiently persuasive or reliable expert opinions supporting their general causation theory. *Id.* at 44.

Despite the almost five pages the Chief Special Master devoted to analyzing (and subsequently rejecting) Petitioners' medical theory, Petitioners argue that the Chief Special Master accepted that their medical theory was plausible, and as such he erred in concluding that they failed to meet their prong one burden. ECF No. 90-1 at 10. In actuality, the Chief Special Master merely noted that the "general gist" of their causation theory "had a baseline level of plausibility." ECF No. 86 at 41. But his analysis of the first *Althen* prong did not stop at this high-level comment; rather, the *Althen* prong one standard required him to evaluate the overall reputability, soundness, and reliability of the posited medical or scientific theory. *See Althen*, 418 F.3d at 1278; *Knudsen*, 35 F.3d at 548–49. Petitioners' attempt to cherry pick a single phrase out of context, when it is clear that the Chief Special Master offered significant analysis dedicated to explaining their theory's deficiencies, fails.

2. The Chief Special Master's Evaluation of Medical Literature Did Not Constitute Legal Error.

Petitioners also allege that the Chief Special Master erred in his evaluation of *Althen*'s first prong by requiring direct evidence from medical literature explaining how the specific vaccines administered to G.J.B. can cause afebrile seizures and by discounting circumstantial evidence used by Petitioners to support their medical theory. ECF No. 90-1 at 14. According to Petitioners, this impermissibly heightened their burden under *Althen* prong one. The Court disagrees.

The Federal Circuit has long recognized that direct proof of a general causation theory is not statutorily required and that petitioners may satisfy the first *Althen* prong with a wide array of circumstantial evidence. *See Althen*, 418 F.3d at 1280 ("[T]he use of circumstantial evidence [is]

envisioned by the preponderance standard."); *Andreu*, 569 F.3d at 1379 ("[A] paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery."); *Knudsen*, 35 F.3d at 549 ("[C]ausation can be found in vaccine cases based on epidemiological evidence and the clinical picture regarding the particular [claimant] without detailed medical and scientific exposition on the biological mechanisms."). As such, a petitioner cannot be faulted for not affirmatively offering any one type of evidence, including medical literature supporting its theory. *See Andreu*, 569 F.3d at 1378 ("Requiring epidemiologic studies . . . or general acceptance in the scientific or medical communities . . . impermissibly raises a claimant's burden under the Vaccine Act[.]" (alterations in original) (citations and internal quotation marks omitted)); *see also Althen*, 418 F.3d at 1280 (holding that requiring a claimant to provide "medical literature . . . contravenes section 300aa-13(a)(1)'s allowance of medical opinion as proof").

But while a "claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment[.]" *Andreu*, 569 F.3d at 1379. In doing so, the special master must view the "medical literature and epidemiological evidence[,] . . . not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard[.]" *Id.* at 1380.

Contrary to Petitioners' argument, the Chief Special Master did not require "direct proof and confirmation" of Petitioners' medical theory, nor did he reject circumstantial evidence in the manner Petitioners allege. *See* ECF No. 90-1 at 10, 14–15. Rather, the Chief Special Master evaluated the evidence presented by Petitioners and found it lacking in applicability, quality, and quantity—and thus insufficient to meet their burden under *Althen*'s first prong. *See* ECF No. 86 at 42–44.

At the outset, the Chief Special Master was careful to recognize that several "Vaccine Program petitioners have successfully established that different vaccines can cause autoimmune injuries featuring or characterized by epileptic seizures." *Id.* at 39 (citing cases). He also acknowledged that petitioners have often times been successful by demonstrating that "the injured child experienced a vaccine-induced fever, which then triggered a *febrile* seizure—thereby instigating epilepsy or some other kind of seizure disorder." *Id.* (emphasis in original). However, because the Chief Special Master found the record did not establish that G.J.B. experienced febrile seizures, he concluded Petitioners' claim "could make limited use of what is known about the association between febrile seizures and vaccines, and needed instead to establish a vaccine association with *afebrile* seizures." *Id.* at 40 (emphasis added).

On this issue, the Chief Special Master first addressed the lack of literature offered by Petitioners proposing causes of afebrile seizures and discussing whether the same pyrogenic cytokine responsible for febrile seizures could cause seizure without fever. *Id.* at 42. He found that the literature filed by Petitioners did "not collectively support that it is likely (even if still not certain) that proinflammatory, pyrogenic cytokines like IL-1β can cause afebrile seizures alone[,]" and that articles filed addressing seizure susceptibility did not "discuss how or why vaccination would be seizure-causing in that context." *Id.* More specifically, the Chief Special Master found that "not enough reliable evidence was offered in this case to conclude that cytokines like IL-1β are likely to cause afebrile seizures simply because some studies show they also play a role in mediating *existing* seizures, or simply by first causing fever." *Id.* (emphasis in original). This finding was supported by literature filed by Respondent suggesting "cytokines are produced secondarily, in *response* to seizure activity." *Id.* (emphasis in original). Accordingly, the Chief Special Master's choice to limit the applicability of febrile seizure research to afebrile seizures and

give little weight to inapt medical literature was part-and-parcel on his factfinding under the first *Althen* prong. Despite Petitioners' assertions to the contrary, this approach was not legal error.

Further, the Chief Special Master also found Plaintiffs offered insufficient evidence connecting the specific vaccines at issue in G.J.B.'s case with the afebrile seizures and specific injuries G.J.B. experienced. *Id.* at 42–43. The Chief Special Master explained that some items of literature cited by Petitioners supported only an association between the MMR vaccine and febrile seizures, cited to the DPT vaccine's association with febrile seizures or other kinds of injuries, left the afebrile association unaddressed, or had been confirmed by Petitioners' experts based on data the experts pulled from larger studies that either contradicted a relationship overall between the vaccines and afebrile seizures or involved samples that were too small to be assigned significant weight. *Id.* (discussing, for example, Wariuru). In contrast, one large epidemiologic study filed by Respondent rejected a relationship between the MMR vaccine and afebrile seizures. *Id.* at 43 (citing Barlow).

Moreover, the Chief Special Master also addressed the quality of evidence offered by Petitioners to support their general causation theory and its pertinence to the circumstances and theory at issue in G.J.B.'s case. *Id.* As he explained, Petitioners over-relied on research pertaining to febrile seizures or other kinds of injuries, derived conclusions from VAERS-like databases that observed only temporal associations between seizure onset and vaccines, and cited case reports that involved facially distinguishable patients. *Id.*

Given the extensive and well-reasoned analysis provided by the Chief Special Master, the Court rejects Petitioners' argument that he improperly discounted evidence because it was circumstantial rather than direct and improperly heightened the legal standard of the first *Althen* prong. The Chief Special Master did not reject the Petitioners' evidence on the ground that it was

circumstantial; rather, he took issue with the quality and quantity of the medical literature, finding the overall support for Petitioners' general causation theory unpersuasive and insufficient to carry their burden. The Court finds no legal error in his evaluation of the evidence.

B. The Chief Special Master's Consideration of An Alternative Explanation of G.J.B.'s Condition Was Not Erroneous.

Petitioners argue that the Chief Special Master erred by considering evidence of an unknown or idiopathic explanation of G.J.B.'s condition when determining whether the preponderance of evidence showed that G.J.B.'s condition was caused by factors unrelated to the administration of the vaccines. ECF No. 90-1 at 14. According to Petitioners, evidence of an idiopathic illness cannot be used to deny recovery to a petitioner. *Id.* at 14–16 (citing 42 U.S.C. §§ 300aa-13(a)(1)(B), 300aa-13(a)(2)). This argument misconstrues the burden shifting framework of the Vaccine Act.

Contrary to Petitioners' claim, the Chief Special Master considered the opinion of Respondent's expert that G.J.B. suffered from epilepsy "of unknown/idiopathic cause" in evaluating whether Petitioners had met their burden under *Althen* prong two. ECF No. 86 at 46; *see id.* at 45–46. The second *Althen* prong requires that a petitioner show a logical sequence of cause and effect between the vaccine and the petitioner's injuries. *See Althen*, 418 F.3d at 1278. This showing is usually supported by evidence from the petitioner's medical records, *id.*; however, the special master may also consider the evidence presented by Respondent to determine whether the petitioner has established this element of his or her prima facie case, regardless of whether the burden of proof ever shifts to Respondent to prove an alternative cause, *Rus v. Sec'y of Health & Hum. Servs.*, 129 Fed. Cl. 672, 680 (2016) (citing *Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012)); *see de Bazan*, 539 F.3d at 1353 ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's

evidence on a requisite element of the petitioner's case-in-chief."). Indeed, the Federal Circuit has held that the Vaccine Act contemplates the special master's consideration of the record as a whole when making his or her entitlement decision, which includes all relevant evidence cited by both parties throughout the proceedings. *See Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1327–28 (Fed. Cir. 2016). As such, "[e]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense [in § 300aa-13(a)(1)(B)], but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question." *Stone*, 676 F.3d at 1379.

In the present case, the Chief Special Master found that Petitioners did not provide sufficient evidence that the vaccines administered to G.J.B. caused his seizure activity. ECF No. 86 at 45–46. Noting the lack of contemporaneous comments by G.J.B.'s treaters supporting vaccine causality, the Chief Special Master instead found better record support for the conclusion that G.J.B. experienced some post-vaccination inflammation, followed by the stuttering and staring that later treaters viewed as reflective of seizure activity. *Id.* at 45. He further found that Petitioners' experts, while positing a causation theory of cytokine impact, did not establish that these early symptoms were caused by the same cytokine response (IL-1β in particular) that would usually cause fever, even though it did not cause fever for G.J.B. *Id.*; *see id.* at 45 n.22 ("[T]here is no evidence in the record that the cytokines Petitioners' experts posit as potentially causal of afebrile seizures were at levels in G.J.B. high enough to produce seizure in him."). Rather, while acknowledging that direct evidence is not required under the Vaccine Act, the Chief Special Master reasoned that the lack of evidence showing the vaccines produced any fever in G.J.B. or that his seizures were febrile, in addition to the absence of test results or information corroborating

Petitioners' theory of cytokine impact, diminished the credibility of finding that Petitioners' theory of causation was occurring in "real time" in G.J.B. *Id.* at 45.

Instead, the Chief Special Master found that evidence presented by Respondent's expert provided a more persuasive alternative explanation for G.J.B.'s condition. *Id.* at 46. In particular, he found that Dr. Shinnar "provided a compelling interpretation of G.J.B.'s history, concluding it likely that an idiopathic origin for G.J.B.'s seizures was the best understanding of the facts, and he rooted this opinion in persuasive evidence suggesting this is how most epilepsy experts would read the medical record in this case." *Id.* Since the Chief Special Master "considered the relevant evidence of record, [drew] plausible inferences and articulated a rational basis for the decision," it was within his discretion to weigh the reliability and credibility of the evidence Petitioners provided to support their theory of causation. *Broekelschen*, 618 F.3d at 1348 (quoting *Hines*, 940 F.2d at 1528). The Chief Special Master did not err by considering both the Petitioners experts' causal theory and Dr. Shinnar's alternative theory of causation, and finding Respondent's interpretation of G.J.B.'s medical history more persuasive than Petitioners', when determining that Petitioners had not made a prima facie showing that the vaccines caused G.J.B.'s injuries. *See Stone*, 676 F.3d at 1379–80.

Because the Chief Special Master did not find preponderant evidence to prove causation-in-fact, the burden of showing an alternative cause by "factors unrelated to the administration of the vaccine" never shifted to Respondent. 42 U.S.C. § 300aa-13(a)(1)(B). And as a result, the exclusion of an "idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition" from the factors unrelated defense does not apply. *Id.* § 300aa-13(a)(2)(A). Consistent with the burden shifting framework, the Chief Special Master expressly disclaimed that he was making (or needed to make) any findings of fact with respect to whether

preponderant evidence proved an alternative cause of or explanation for G.J.B.'s seizures. *See* ECF No. 86 at 45–46.

Accordingly, the Chief Special Master did not err with respect to *Althen* prong two because he appropriately considered all the relevant evidence in the record to determine whether Petitioners had successfully established causation, including Dr. Shinnar's opinion that G.J.B.'s epilepsy was idiopathic.

IV. CONCLUSION

The Court finds that the Chief Special Master's examination of the record in Petitioners' case, including the multiple expert reports, G.J.B.'s contemporaneous medical records, and the literature submitted, resulted in a decision that was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). The Chief Special Master's Entitlement Decision is therefore affirmed, and Petitioners' Motion for Review (ECF No. 90) is **DENIED**. The Clerk of the Court shall enter **JUDGMENT** consistent with this Opinion.

This Opinion and Order will be unsealed in its entirety after December 5, 2023, unless pursuant to Vaccine Rule 18(b) the parties specifically identify protected and/or privileged information subject to redaction prior to that date. Any objecting party must submit a proposed redacted version of the decision and provide the reason(s) supporting the party's request for redaction.

SO ORDERED.

Dated: November 20, 2023

/s/ Kathryn C. Davis
KATHRYN C. DAVIS
Judge